ISRCTN97265287 https://doi.org/10.1186/ISRCTN97265287

Testing a laser tool for finding cavities in kids' molars

Submission date	Recruitment status	[_] Prospectively registered
22/07/2024	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
29/07/2024	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
29/07/2024	Oral Health	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Dental caries, or tooth decay, is a common problem that affects many people worldwide, especially on the chewing surfaces of the back teeth (molars). Early and accurate detection of caries is crucial for effective treatment and preventing further damage. This study aims to evaluate a tool called DIAGNOdent, which uses laser technology to detect caries on the chewing surfaces of teeth. The researchers want to see if this tool is as good as or better than traditional methods of visual examination in detecting different stages of caries.

Who can participate?
Children who are 7 years old and have first permanent molars that do not have any existing restorations or fissure sealants can participate. Participants must be generally healthy and have not had fluoride varnish treatment in the past 6 months.

What does the study involve?
Participants will have their teeth examined using both traditional visual methods and the DIAGNOdent laser tool. The DIAGNOdent tool will measure how much the teeth fluoresce (glow) under a laser light, which helps in detecting caries. The researchers will compare the results from both methods to see how well DIAGNOdent works in identifying carious lesions.

What are the possible benefits and risks of participating?
The benefits of participating include early detection of carious lesions, which can help in planning effective treatments and potentially preventing more serious dental issues. The risks are minimal but may include slight discomfort during the examinations or the need for additional dental visits.

Where is the study run from?
Kalamoun University (Syria)

When is the study starting and how long is it expected to run for?
February 2015 to March 2015

Who Is funding the study?
University of Kalamoon (Syria)

Who Is the main contact?
Dr Massa Mahayni, massa1.mahayni@damascusuniveristy.edu.sy

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Massa Mahayni

ORCID ID
https://orcid.org/0009-0002-2037-1514

Contact details
Mezzah
Damascus
Syria
445
+963 (0)941113368
massa1.mahayni@damascusuniversity.edu.sy

Additional identifiers

Study information

Scientific Title
Evaluating the efficacy of DIAGNOdent laser fluorescence in detecting occlusal caries: a clinical study

Acronym
EDL-FIND

Study objectives
The DIAGNOdent laser fluorescence method is more effective than traditional visual examination in detecting occlusal caries in permanent molars of children, particularly at different thresholds for caries severity.

Ethics approval required
Ethics approval not required

Ethics approval(s)
The study titled “Evaluating the Efficacy of DIAGNOdent Laser Fluorescence in Detecting Occlusal Caries: A Clinical Study” does not require formal ethics approval based on the following reasons:

Non-Invasive and Routine Procedures: The research involves the use of the DIAGNOdent laser fluorescence device to detect occlusal caries, which is a non-invasive diagnostic procedure commonly used in dental practice. No new or experimental interventions are being tested.

Standard Clinical Practice: The study utilizes standard diagnostic tools and procedures that are already part of routine clinical practice. It does not involve experimental treatments or procedures that would warrant additional ethical scrutiny.

No Risk of Harm: The study does not pose any physical, psychological, or emotional risk to participants. The diagnostic procedures are safe, and the study does not involve any invasive or potentially harmful interventions.

Use of Existing Data: The research does not involve the collection of sensitive personal data beyond what is typically collected in a standard dental diagnostic setting. Any data collected is anonymized and used solely for the purpose of evaluating the efficacy of the diagnostic tool.

Informed Consent: All participants were provided with clear information about the study and provided with informed consent before participating. This ensures transparency and respects participants' rights.

Compliance with Regulations: The study complies with relevant regulations and guidelines for clinical research. It follows standard practices and does not deviate from accepted procedures that are already ethically vetted in routine clinical settings.

In summary, because the study involves standard diagnostic procedures without introducing new risks or interventions, and since informed consent is obtained, it does not necessitate formal ethics approval.

Primary study design
Observational

Study design
Clinical diagnostic study

Study type(s)
Diagnostic, Efficacy

Health condition(s) or problem(s) studied
Occlusal caries

Interventions
The study will evaluate the efficacy of the DIAGNOdent laser fluorescence method for detecting occlusal caries compared to visual examination.

The methodology involves:
1. Participant Selection: A total of 120 first permanent molars from 30 children aged 7 years will be examined. Participants will be selected from the clinics of the Faculty of Dentistry at Kalamoun University.

2. Diagnostic Procedures:
2.1. Visual Examination: The occlusal surfaces will be examined using a dental mirror and a World

Health Organization (WHO) periodontal probe. Lesions will be classified into three grades: sound (Grade 0), white/brown spot lesions (Grade 1), and cavitated caries lesions (Grade 2).
2.2. DIAGNOdent Examination: The DIAGNOdent laser fluorescence device will be used to assess the fluorescence levels on the same occlusal surfaces. Readings will be classified into three categories based on the manufacturer's cut-off points: sound (0-5), histological enamel caries (6-14), and histological dentinal caries (≥15).
3. Data Collection: The results from both diagnostic methods will be recorded. Sensitivity, specificity, accuracy, and inter-method agreement will be analyzed to determine the performance of DIAGNOdent compared to visual examination.
4. Analysis: The study will compare the DIAGNOdent readings with visual examination results using statistical methods, including sensitivity, specificity, and Cohen’s kappa coefficient to assess inter-method reliability.

Intervention Type
Other

Primary outcome(s)
Occlusal caries detection is measured using DIAGNOdent laser fluorescence and visual examination at baseline

Key secondary outcome(s)
1. Sensitivity and specificity of DIAGNOdent measured using the DIAGNOdent laser fluorescence device and visual examination at baseline
2. Accuracy of DIAGNOdent measured by comparing DIAGNOdent readings with visual examination results at baseline
3. Inter-method agreement between DIAGNOdent and visual examination measured using Cohen's kappa coefficient at baseline

Completion date
29/03/2015

Eligibility

Key inclusion criteria
1. Children aged 7 years
2. Participants must have first permanent molars without occlusal restorations or fissure sealants
3. Participants must have visible occlusal caries or be in need of evaluation for caries
4. Participants must be in generally good health with no significant systemic diseases
5. Participants must not have received fluoride varnish treatment within the past 6 months

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit

7 Years

Upper age limit
7 Years

Sex
All

Total final enrolment
120

Key exclusion criteria
1. Participants with significant systemic diseases that could affect the study's outcomes or procedures
2. Participants who have received fluoride varnish treatment within the past 6 months
3. Participants with occlusal restorations, fissure sealants, or hypoplastic pits on the first permanent molars
4. Participants whose guardians are unable or unwilling to provide informed consent
5. Participants who are unable to cooperate with the study procedures or examinations

Date of first enrolment
01/03/2015

Date of final enrolment
03/03/2015

Locations

Countries of recruitment
Syria

Study participating centre
university of kalamoon
Deir Attyeh
Damascus
Syria
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Sponsor information

Organisation
University of Kalamoon

ROR
https://ror.org/02g847680

Funder(s)

Funder type
University/education

Funder Name
University of Kalamoon

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Massa Mahayni (massa.mahayni@gmail.com).
Type of data shared: anonymized diagnostic test results and demographic information
Participant consent: informed consent was obtained from all participants, ensuring their awareness of data usage.
Data anonymization: all participant data will be fully anonymized to protect personal information.
Ethical/legal restrictions: there are no ethical or legal restrictions anticipated for sharing the anonymized data.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			23/07/2024	No	Yes
Protocol file			26/07/2024	No	No
Statistical Analysis Plan			26/07/2024	No	No